K111909

OCT 18 2011

510(k) SUMMARY

VITEK® 2 *Streptococcus* Inducible Clindamycin Resistance

510(k) Submission Information:

Submitter's Name:	bioMérieux, Inc.
Address:	595 Anglum Road Hazelwood, MO 63042
Contact Person:	Nathan Hardesty Senior Regulatory Affairs Specialist
Phone Number:	314 -731-8666
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Date of Preparation:	June 30, 2011

B. Device Name:

Formal/Trade Name:	VITEK® 2 *Streptococcus* Inducible Clindamycin Resistance
Classification Name:	21 CFR 866.1645 Fully Automated Short-Term Incubation Cycle Antimicrobial Susceptibility System Product Code LON
Common Name:	VITEK® 2 AST-ST Inducible Clindamycin Resistance

C. Predicate Device: VITEK® 2 Gram Positive Inducible Clindamycin Resistance (K080201)

D. 510(k) Summary:

VITEK® 2 *Streptococcus* Inducible Clindamycin Resistance is designed for antimicrobial susceptibility testing of *Streptococcus agalactiae* & *Streptococcus pyogenes*. VITEK® 2 *Streptococcus* Inducible Clindamycin Resistance is a qualitative test. It is intended for use with the VITEK® 2 and VITEK® 2 Compact Systems as a laboratory aid in the determination of *in vitro* susceptibility to antimicrobial agents.

The antimicrobial presented in VITEK® 2 AST-ST Cards are in concentrations equivalent by efficacy to standard method concentrations in mcg/ml. The VITEK® 2 AST Cards are essentially miniaturized versions of the doubling dilution technique for determining the minimum inhibitory concentration (MIC) microdilution methodology.

The isolate to be tested is diluted to a standardized concentration in 0.45 - 0.50% saline before being used to rehydrate the antimicrobial medium within the card. The VITEK® 2 automatically fills, seals and places the card into the incubator/reader. The VITEK® 2 Compact has a manual filling and sealing operation. The VITEK® 2 monitors the growth of each well in the card over a defined period of time (up to 18 hours). At the completion of the incubation cycle, a report is generated that contains the MIC value along with the interpretive category result for each antimicrobial contained on the card.

VITEK® 2 *Streptococcus* Inducible Clindamycin Resistance demonstrated substantially equivalent performance when compared with the CLSI Interpretive Criteria, as defined in the FDA Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems; Guidance for Industry and FDA. Issued August 28, 2009.

The Premarket Notification (510[k]) presents data in support of VITEK® 2 *Streptococcus* Inducible Clindamycin Resistance. An external evaluation was conducted with fresh and stock clinical isolates, as well as a set of challenge strains. The external evaluations were designed to confirm the acceptability of VITEK® 2 *Streptococcus* Inducible Clinidamycin Resistance by comparing its performance with the CLSI Interpretive Criteria incubated at 24 hrs. The data is representative of performance on both the VITEK® 2 and VITEK® 2 Compact instrument platforms. VITEK® 2 *Streptococcus* Inducible Clindamycin Resistance demonstrated acceptable performance of 99.2% overall category agreement with the reference method. Reproducibility and Quality Control demonstrated acceptable results.

TPLC Detailed View from 1/01/2008 to 8/2

Product Code	
Manufacturer	
Class	
Regulation Device Classification	
Device Name	
Date Last Listed	**Not Listed**

CDRH Gen Docs without Manufacturer (None)

Premarket Reviews Completed (None)

Under Review, Withdrawn or Closed without Product Code (None)

Standards and Guidance (None)

MDR Summary (None)

MDR Analyst (None)

MDR Distribution by Brand - Death or Injury (None)

Patient Problems (None)

Patient Outcomes (None)

Device Problems (None)

Manufacturer Evaluation Results (None)

Manufacturer Evaluation Conclusions (None)

Recalls (None)

Inspections (None)

CDRH Gen Docs without Manufacturer (None)

Rad Health Reports (None)

Rad Health Correspondence (None)

Rad Health Adverse Events (None)

Rad Health EIRs (None)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

OCT 18 2011

bioMérieux, Inc.
c/o Nathan Hardesty
Sr. Regulatory Affairs Specialist
595 Anglum Rd.
Hazelwood, Missouri 63042

Re: k111909
Trade/Device Name: VITEK® 2 *Streptococcus* Inducible Clindamycin Resistance
Regulation Number: 21 CFR§ 866.1645
Regulation Name: Short-Term Antimicrobial Susceptibility Test System
Regulatory Class: Class II
Product Code: LON
Dated: October 17, 2011
Received: October 17, 2011

Dear Mr. Hardesty:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111909

Device Name: VITEK® 2 *Streptococcus* Inducible Clindamycin Resistance

Indications For Use:

VITEK® 2 *Streptococcus* Inducible Clindamycin Resistance is designed for antimicrobial susceptibility testing of *Streptococcus agalactiae* and *Streptococcus pyogenes*. VITEK® 2 *Streptococcus* Inducible Clindamycin Resistance is a qualitative test. It is intended for use with the VITEK® 2 and VITEK® 2 Compact Systems as a laboratory aid in the determination of in vitro susceptibility to antimicrobial agents.

The VITEK® 2 Antimicrobial Susceptibility Test (AST) is intended to be used with the VITEK® 2 Systems for the automated quantitative or qualitative susceptibility testing of isolated colonies for the most clinically significant aerobic Gram-negative bacilli, *Staphylococcus* spp., *Enterococcus* spp., *Streptococcus* spp. and yeast.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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